

REMARKS

Applicants confirm the provisional election, without traverse, of the invention of Group I and of the species identified as the sub-xyphoid approach.

Copies of the two Forms PTO-1449 previously submitted in this case were transmitted with the Office Action. However, these forms were not signed or initialed. Applicants request that the Forms PTO-1449 be initialed and signed to indicate that the references listed in those forms have been considered by the Examiner.

The correspondence address for this application has been changed. This change has been implemented by filing a Request for Customer Number Data Change for Customer Number 33109, with which this application is associated. For the convenience of the Examiner, the new correspondence address is:

Cardica, Inc.
900 Saginaw Drive
Redwood City, CA 94063

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-2, 7, 11-17

Amended claim 18 claims, among other elements, a method including "performing a sutureless proximal anastomosis between the graft vessel and one target vessel while the heart is beating," and "performing a sutureless distal anastomosis between the graft vessel and another target vessel with at least one tool while the heart is beating."

In contrast, U.S. Pat. No. 5,735,290 to Sterman ("Sterman") neither teaches nor suggests all of the elements of claim 1. For example, Sterman neither teaches nor suggests performing proximal or distal anastomosis while the heart is beating. Instead, the method of Sterman requires that the heart be stopped before anastomosis is performed:

it is necessary to place the patient on cardiopulmonary bypass and to induce cardioplegia (*i.e.*, stop cardiac contraction) prior to connecting the arterial graft to the coronary artery. (column 9, lines 40-43). (emphasis added).

That is, in the procedure of Sterman, the heart must be stopped before anastomosis is performed. The heart is restarted after anastomosis is complete. (column 14, lines 44-46). Sterman not only fails to disclose performing anastomosis while the heart is beating, but also teaches away from performing anastomosis while the heart is beating. For example, Sterman provides an extensive disclosure as to the use of an aortic occlusion catheter to confine cardioplegic fluid to the heart and proximal ascending aorta (column 9, lines 51-56), and also gives detailed directions for stopping the heart (column 11, line 36 through column 13, line 17).

Further, Sterman is directed to an anastomosis between a single end of a mammary artery and a coronary artery, such that only one anastomosis—the proximal anastomosis—need be performed. (*e.g.*, column 7, line 65 through column 8, line 13). The other end of the mammary artery is undisturbed and remains in place. Sterman mentions in passing that "free grafts...formed from veins or arteries harvested from other locations in a patient's body" may be used in lieu of a mammary artery. (column 8, lines 19-27). Such a free graft is said to be "attached at one end to the proximal ascending aorta...and at the other end to the target location on the coronary artery." (column 8, lines 25-27). However, Sterman discloses no method or structure for connecting an end of a graft vessel to the proximal ascending aorta, thereby providing no enablement or written description for anastomosis between that free

graft and the aorta. Because Sterman provides no enablement or written description for connecting a graft vessel to the aorta, it is not a valid reference with regard to performing a proximal anastomosis. Consequently, Sterman neither teaches nor suggests each and every element claimed in claim 1.

Thus, Applicants believe claim 1 is in condition for allowance. The Examiner has admitted on the record, in the Office Action of July 11, 2003, that claim 1 is generic. Thus, were it to be allowed, claim 1 would be allowed as to all species identified in this application.

Claims 2, 7 and 11-17 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III). Thus, Applicants do not and need not concede to any characterization of these dependent claims in the Office Action.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claim 3

The rejection of claim 18 in the Office Action is believed to be directed at claim 3, based on the content of the rejection; as such, claim 3 will be addressed here rather than claim 18. As described above, Sterman does not teach or suggest every element of amended

claim 1. Claim 3 depends indirectly from claim 1, and thus includes all of the limitations of claim 1. Thus, Sterman cannot and does not teach or suggest every element of claim 3, and the combination of Sterman and Wolf cannot teach nor suggest all of the limitations of claim 3.

Further, because amended claim 3 depends indirectly from claim 1, which is believed to be allowable, claim 3 is in condition for allowance under MPEP 608.01(n)(III).

Claim 8

As described above, Sterman does not teach or suggest every element of amended claim 1. Claim 8 depends indirectly from claim 1, and thus includes all of the limitations of claim 1. Thus, Sterman cannot and does not teach or suggest every element of claim 8, and the combination of Sterman and Popov cannot teach nor suggest all of the limitations of claim 8.

Further, because claim 8 depends from claim 1, which is believed to be allowable, claim 8 is in condition for allowance under MPEP 608.01(n)(III).

Claims 1, 10

As described above, Sterman does not teach or suggest every element of amended claim 1. Thus, the combination of Sterman and Popov cannot and does not teach nor suggest all of the limitations of claim 1.

Further, because claim 10 depends from claim 1, which is believed to be allowable, claim 10 is in condition for allowance under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of pending claims 1-8 and 10-18 with regard to all species is respectfully requested. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 364-9975 x162
Chief Patent Counsel
Cardica, Inc.